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PCCP Manufacturer Feedback Questionnaire

Based on *FDA Final Guidance*
(All underlined text contains hyperlinks to the referenced documents.)
"Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions"
(Final Guidance – December 4, 2024; Docket No. FDA-2022-D-2628)

Thank you for taking part in our PCCP Manufacturer Feedback Survey, conducted by the ***Else Kröner Fresenius Center for Digital Health*** **at Technical University Dresden (Germany)** under the leadership of **Prof. Dr. Stephen Gilbert** (stephen.gilbert@tu-dresden.de). Professor Gilbert is the head of the Medical Device Regulatory Science Group. Your responses will inform the development of best practices for AI/ML-enabled medical device change management.

Total Sections: 6 Total Questions: 25-30 Time: 15-20 minutes

Continue

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This questionnaire is for scientific research purposes only. All responses will remain confidential. Only aggregated insights will be shared publicly. No company- or device-identifiable data will be disclosed.

Instructions for Manufacturers
You have two options for submitting feedback:

1. Completely Anonymous – you do **not** need to provide Submission Numbers or Device Names. Your feedback will remain fully confidential, and no identifiable data will be shared with us.

2. Optional Information – you **may** provide Submission Numbers and Device Names. Providing your Submission Numbers and Device Names **helps us** link feedback to specific device types—allowing deeper, more actionable insights—while still ensuring that **only aggregated**, **non-identifiable results are shared in scientific publications**.

Continue press Enter ↵

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1 → Submission Numbers (Optional)

Type your answer here...

OK press Enter ↵

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2 → Device Names (Optional)

Type your answer here...

OK press Enter ↵

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3 → What was the primary rationale for including a PCCP in your marketing submission? *e.g., more efficient change management, on-market adaptation/self-learning, resource predictability, etc.*

Type your answer here...

Shift ⇧ + **Enter** ↵ to make a line break

OK press **Enter** ↵

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4 → How clear and useful was the *FDA final guidance* in supporting your PCCP preparation and submission?

- A Clear & easy to apply
- B Clear but difficult to apply
- C Unclear but easy to apply
- D Unclear & difficult to apply
- E Prefer not to answer

OK

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5 → Which elements of the guidance were especially **helpful**, and why?
e.g., terminology, examples, interpretive flexibility, structure, alignment with practice, transparency.

Type your answer here...

Shift ⇧ + Enter ↵ to make a line break

OK press **Enter ↵**

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6 → Which elements of the guidance were **difficult** to interpret or apply, and why? *e.g., scope boundaries, risk-interpretation, justification requirements, process burden.*

Type your answer here...

Shift ⇧ + Enter ↵ to make a line break

OK press **Enter ↵**

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In this section (Q7–12), your experience with preparing each of the three PCCP sections will be asked:

VI. Description of Modifications
VII. Modification Protocol
VIII. Impact Assessment

Continue press Enter ↵

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7 → Please rate the difficulty your team encountered when preparing PCCP section VI: **Description of modification**

1 – Not at all challenging 2 – Slightly challenging 3 – Moderately challenging 4 – Very challenging 5 – Extremely challenging

1 2 3 4 5

OK

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8 → Please describe any difficulty or success you had with navigating the **Description of modification** section.

Type your answer here...

Shift ⇧ + Enter ↵ to make a line break

OK press **Enter ↵**

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9 → Please rate the difficulty your team encountered when preparing PCCP section VII: **Modification Protocol**

1 – Not at all challenging 2 – Slightly challenging 3 – Moderately challenging 4 – Very challenging 5 – Extremely challenging

1 2 3 4 5

OK

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10 → Please describe any difficulty or success you had with navigating the **Modification Protocol** section.

Type your answer here...

Shift ⇧ + Enter ↵ to make a line break

OK press **Enter ↵**

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11 → Please rate the difficulty your team encountered when preparing PCCP section VIII: **Impact Assessment**

1 – Not at all challenging 2 – Slightly challenging 3 – Moderately challenging 4 – Very challenging 5 – Extremely challenging

1 2 3 4 5

OK

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12 → Please describe any difficulty or success you had with navigating the **Impact Assessment** section.

Type your answer here...

Shift ⇧ + Enter ↵ to make a line break

OK press **Enter ↵**

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13 → Have you used the *FDA's Q-Submission Program* to get feedback on your proposed PCCP before submitting a marketing application?

Y Yes

N No

OK

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14 → How useful was the FDA's feedback during the Q-Submission process for improving your PCCP?

- A 1 – Not at all useful
- B 2 – Slightly useful
- C 3 – Moderately useful
- D 4 – Very useful
- E 5 – Extremely useful
- F Prefer not to answer

OK

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15 → Did FDA feedback during Q-Submission significantly alter your overall PCCP approach?

Y Yes

N No

OK

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16 → Which aspects of your PCCP did FDA feedback lead you to revise? (select all that apply)

- [A] Description of Modifications
- [B] Modification Protocol
- [C] Impact Assessment
- [D] Risk mitigation strategies
- [E] Study/design parameters or testing plans
- [F] Project timelines or milestones
- [G] Resource allocation or staffing levels
- [H] Regulatory strategy or submission type
- [I] Other (please specify)
- [J] Prefer not to answer

OK

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17 → "If you chose '**Other**' in the previous question, please describe which additional PCCP element(s) you revised based on FDA feedback and explain what changes you made."

Type your answer here...

Shift ⇧ + **Enter** ↵ to make a line break

OK press **Enter** ↵

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18 → How many distinct design modifications are included in your device ´s PCCP? Select the total number of planned change types *(e.g., model retraining; threshold tuning; preprocessing/postprocessing; architecture adjustments; new modalities; UI/workflow improvements; feature additions; performance optimization*):

- A 1 change
- B 2 changes
- C 3 changes
- D 4 changes
- E More than 4 changes
- F Prefer not to answer

OK

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19 → Indicate the current adaptiveness of the AI algorithm in your PCCP submission:

- A Fully locked (no learning post-deployment)
- B Locked with occasional manual updates
- C Retrainable under PCCP, but not self-adaptive
- D Adaptive with limited autonomy (e.g., local tuning only)
- E Prefer not to answer

OK

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20 → Indicate your preferred future adaptiveness of the AI algorithm (2–5 year outlook):

- A Fully locked
- B Manually retrained only
- C Retrainable on new data with external oversight
- D Adaptive with internal triggers and safety checks
- E Fully self-learning and self-updating in the field
- F Prefer not to answer

OK

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21 → How would you characterize your experience using the PCCP concept on your own devices?

- A 1 – Not at all effective
- B 2 – Slightly effective
- C 3 – Moderately effective
- D 4 – Very effective
- E 5 – Highly effective
- F Prefer not to answer

OK

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22 → To what extent did the PCCP concept meet your expectations for managing post-market device modifications (overall approach)?

- A 1 – Not at all effective
- B 2 – Slightly effective
- C 3 – Moderately effective
- D 4 – Very effective
- E 5 – Highly effective
- F Prefer not to answer

OK

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23 → If your future AI/ML-enabled device would be eligible for a PCCP, would you choose to use the PCCP pathway in future submissions?

- A Yes, definitely worth it
- B Maybe – if the change complexity justifies a PCCP pathway
- C No, it's too burdensome
- D Prefer not to answer

OK

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24 → Which aspects of the PCCP concept are you **satisfied** with, and why? *e.g., implementation practicality, evidence requirements, lifecycle flexibility, clarity of change boundaries, QMS alignment, FDA predictability, efficiency gains over supplements.*

Type your answer here...

Shift ⇧ + Enter ↵ to make a line break

OK press **Enter ↵**

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25 → Which aspects of the PCCP concept are you **not satisfied** with, and why? *e.g., complexity, evidence burden, ambiguous boundaries, limited flexibility, misalignment, unpredictability, documentation intensity.*

Type your answer here...

Shift ⇧ + Enter ↵ to make a line break

OK press **Enter ↵**

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26 → From a regulatory-professional standpoint (workload, process clarity/functionality), how does PCCP compare to traditional change processes (e.g., Special 510(k), PMA supplements)?

- A 1 – Strong preference for traditional processes
- B 2 – Some preference for traditional processes
- C 3 – No preference
- D 4 – Some preference for PCCP
- E 5 – Strong preference for PCCP
- F Prefer not to answer

OK

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27 → Please explain your reasoning and key factors that shaped your preference:

Type your answer here...

Shift ⇧ + Enter ↵ to make a line break

OK press **Enter ↵**

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28 → To what extent do you agree that the PCCP provides overall advantages—such as improved customer satisfaction and commercial success—that justify the effort required?

- A 1 – Strongly disagree (significantly less favorable)
- B 2 – Disagree (less favorable)
- C 3 – Neither more nor less favorable
- D 4 – Agree (more favorable)
- E 5 – Strongly agree (significantly more favorable)
- F Prefer not to answer

OK

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29 → Which strategic view best describes your organization?

- A PCCP adds value & is easy to integrate
- B PCCP adds value & is hard to integrate
- C PCCP lacks value & is easy to integrate
- D PCCP lacks value & is hard to integrate
- E Prefer not to answer

OK

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30 → Please describe the impact on your organization's product lifecycle or strategic alignment: *e.g., lifecycle acceleration, innovation enablement, resource planning, scalability, long-term QA, budgeting, strategic fit.*

Type your answer here...

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OK press **Enter ↵**

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31 → Would you be open to a 15-minute, one-on-one interview about your experience preparing and submitting a PCCP?

Y Yes

N No

OK

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32 → If “Yes,” please provide your email address:

name@example.com

OK press Enter ↵

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" Thank you for your valuable feeback !

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Submit press Ctrl + Enter ↵